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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,681	06/27/2003	David Wynn	MCP-5016 NP	8293

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EXAMINER	
BROWN, COURTNEY A	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,681	WYNN ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/2003 and 10/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on March 11, 2008 is acknowledged. Claims 1-20 are pending and are being examined for patentability. Claim 6 remains withdrawn. Thus claims **1-5, 7-20** are under examination.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Information Disclosure Statement

The Information Disclosure Statements (IDS) submitted on September 6, 2003 and October 14, 2004 have been considered by the examiner.

Claim Rejections - 35 USC § 112

Applicant's arguments see page 2, filed March 11, 2008, with respect to the rejections under 35 USC 112 first and second paragraphs have been fully considered and are persuasive. The 35 USC 112 Rejections of claims 12 and 13 have been withdrawn.

Double Patenting

Applicant's arguments, see page 3, filed March 11,2008, with respect to the Obviousness Double Patenting Rejection of claims 1-5 and 7-20 have been fully

considered and are not persuasive. Applicant believes that the obviousness-type double patenting rejections are moot as the subject matter of the present application has yet to issue into a patent. Thus, the nonstatutory obviousness-type double patenting rejection is maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 8-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-35 of Application No. 10/607,776. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by the co-pending application.

The copending application is directed to the same immediate release dosage form comprising a plurality of particles comprising a pharmaceutically active ingredient,

and a matrix comprising hydroxyalkylcellulose and a water-disintegratable compressible carbohydrate. The difference between the instant invention and that of Application 10/607,766 is that the instant invention does not require the use of a taste masking coating. One of ordinary skill in the art would be motivated not to include the use of a taste masking coating because the pharmaceutical ingredients of the instant invention may be of desirable taste or palpable. Therefore, there would be no need to use a taste masking coating. Additionally, According to MPEP 2111.03 [R-3], the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Hence, the use of "comprising" language in the instant claims would allow for the inclusion of a taste masking coating.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims **1-5 and 7-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuter et al. (U.S. 4,835,187) in view of Dressman et al. (U.S. 5,789,393), and further in view of Siebert et al. (WO 00/09090).

Applicant's Invention

Applicant claims an oral immediate release dosage in the form of a tablet comprising: a.) a plurality of particles comprising a pharmaceutically active ingredient having a particle size of about 150-400µm selected from the group consisting of acetaminophen, acetyl salicylic acid, ibuprofen, naproxen, ketoprofen, flurbiprofen, diclofenac, cyclobenzaprine, meloxicam, rofecoxib, celecoxib, and pharmaceutically acceptable salts, esters, isomers, and mixtures thereof and b.) a matrix (wherein the plurality of particles comprised of a pharmaceutically active ingredient are substantially free of hydroxyalkycellulose) comprising 1-25% hydroxypropylmethylcellulose having a weight average MW of from about 140,000 to about 1,150,000 Daltons and a viscosity of from about 3,000 mPa.S to about 150,000 mPa.S in a 2% aqueous solution and 50-80% of a water-disintegratable compressible carbohydrate selected from the group consisting of dextrose monohydrate, mannirtol, srobitrol, xylitol, and mixtures thereof. Applicant further limits the invention to being a dosage form that meets USP dissolution requirements for immediate release form of said pharmaceutically active ingredient and having a moisture content of not more than about 5% as measured by weight loss on drying at 105 degrees Celsius.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Reuter et al. teach an immediate release composition in chewable solid dosage form comprising: a plurality of inert silica particles of about 10 millimicrons (i.e., 10 nm or 0.01 pm) comprising ibuprofen, which is present in an amount of from about 40 wt.%

to about 70 wt.%; USP hydroxypropylmethylcellulose grades E, F and K (e.g., Methocel/HPMC E4MP) having a viscosity ranging from about 3,500 centipoise to about 5,600 centipoise (i.e., from about 3,500 mPa.s to about 5,600 mPa.s) and present in an amount ranging from 15 wt.% to about 50 wt.%; and mannitol (abstract; column 1, lines 1-68; column 2, lines 1-68; column 3, lines 6-68; column 4, lines 6, 22 and 56-68;and column 5, lines 1-9). Reuter et al. further teach incorporating taste-neutral ibuprofen powder in pharmaceutical dosage forms for oral administration (column 1, lines 45-61 and claims 1-9).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the invention of the instant application and that of Reuter et al. is that the instant invention requires a matrix comprising the hydroxyproylmethylcellulose (HPMC). It is for this reason that the teaching of Dressman et al. is joined. Dressman et al. teach pharmaceutical compositions using cellulose ethers (title). Dressman et al. teach that a 2% aqueous solution of a high molecular weight HPMC has a viscosity of about 30,000 mPa.S and that rheological studies have confirmed that a very high molecular weight HPMC of about 400,000 mPaS at 20 degrees Celsius in a 2% aqueous solution produces a viscosity equivalent to 30,000 cP at a concentration of 1.5% (column 19, lines 65 to column 20, lines 1-5).

Another difference between the invention of the instant application and that of Reuter et al. is that the instant invention requires that the particle diameters ranging from about 150 μm to about 400 μm and the weight percentage of the water-

disintegratable compressible carbohydrate range from about 50 to about 80 percent. Siebert et al. teach the use of microcapsules having a particle size ranging form between about 50 to about 3,000 microns (μm) (see page 4, lines 3-5). Additionally, Siebert et al. teach the use of 5-60% of a sugar or a sugar alcohol (page 4, lines 8-10). Siebert et al. list examples of sugar and sugar alcohols such as mannitol, sorbitol, and xylitol (see page 11, lines 23-26).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Reuter et al., Dressman et al., and Siebert et al to devise a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing. One would be motivated to combine these teachings because the claimed limitations on the molecular weight of hydroxyproylmethylcellulose would also have been obvious to one of ordinary skill in the art because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Thus since the use of hydroxyproylmethylcellulose within applicants claimed MW range was already well known to be useful in pharmaceutical compositions as shown by Dressman. Applicant's claimed hydroxyproylmethylcellulose was a known option available at the time of the invention and someone of ordinary skill in the art would have a high

expectation of success using the specific MW of hydroxyproylmethylcellulose disclosed. This is also true for claimed particle diameters and the weight percentage of the water-disintegratable compressible carbohydrate as taught by Siebert et al.

It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining Reuter et al. with Dressman and Siebert et al., as claimed in the instant invention, sets forth prima facie obvious subject matter.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on March 11, 2008 have been fully considered but they are not persuasive. Applicant argues that Dressman et al. and Siebert et al. do not disclose or suggest the use of cellulose ethers in combination with "a plurality of particles comprising a pharmaceutically active ingredient" as recited in claims 1 and 14 of the instant application. However, the secondary teaching of Dressman et al. was bought in to show that the use of hydroxypropylmethylcellolose in a pharmaceutical composition was known at the time of the instant invention. Hence, whether or not the formulation of cellulose ethers are in combination with or without "a plurality of particles comprising a pharmaceutically active ingredient" would not preclude one of ordinary skill from its selection.

Additionally, Applicant points to page 11, lines 3-6 of the specification wherein Applicant "unexpectedly found that the addition of high weight average molecular weight hydroxyalkylcellulose to the matrix results in a dosage form that delivers a good mouth feel through a rapid viscosity build without an initial intense drying sensation of the mouth and without a subsequent excessive slimy or gummy feel during mastication." This is not persuasive because this aspect of the instant application is not commensurate with the scope of the claims.

Conclusion

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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